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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,694	12/21/2004	Michael Chopp	1059.00106	2465

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KOHN & ASSOCIATES, PLLC
30500 NORTHWESTERN HWY
STE 410
FARMINGTON HILLS, MI 48334

EXAMINER	
WEBB, WALTER E	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
03/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,694	CHOPP, MICHAEL	
	Examiner	Art Unit	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112 (Previous)

The written description rejection of claims 1-13 is maintained and applies to claims 1-4 and 6-13.

Applicant argues that stroke induced neurogenesis in the adult rat and mouse has been demonstrated. Applicant cited references supporting demonstration of stroke-induced neurogenesis in the adult human brain. Nevertheless, the lack of support in the disclosure for "promoting neurogenesis" has not been properly addressed. Applicant argues that they "predicted that administration of MSCs promotes endogenous neurogenesis in stroke patients" based on the prior art. However, the description requirement of the patent statute requires a description of the invention, not an indication of a result that one might achieve if one made that invention. See. E.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984).

New Matter Rejection (New Rejection)

Claims 1-4 and 6-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "new matter" rejection.

No support is seen in the specification as originally filed for the amended phrase "identifying increased numbers of new neurons." Applicant has not described this phrase in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102 (Previous)

Claims 1, 3, 5-8, 10 and 12 were rejected under 35 U.S.C. 102(b) as being anticipated by Graham (US 6,075,028). This rejection is maintained with regard to claims 1, 3, 6-8, 10, and 12.

Applicant argues that Graham is not anticipatory since the doses of sildenafil used in Applicant's studies are higher than doses used in Graham. They also argued that their invention is useful for patients suffering from neural injury and Tourette's syndrome is not a form of neural injury. However these features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant also amended claims to include the limitation "identifying increased numbers of new neurons." However, this limitation does not necessarily overcome the

rejection of based on Graham, since a way of identifying increased numbers of new neurons would be to recognize improvement in the disease after administration.

In response to applicants argument that Graham does not disclose an "effective amount" to promote neurogenesis, the term "effective amount", as outlined in MPEP 2173.05(c) III, is a very broad functional term, which in fact, is sometimes considered indefinite. Without more, the invention of Graham is capable if performing the intended use.

Applicant argues that since it was not known that sildenafil could regenerate neurons or grow new nerves, Graham cannot perform the present invention. However, "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Therefore, the fact that Graham does not teach regeneration of neurons does not make this undisclosed function patentable.

The rejection of claims 3 and 4 under 35 U.S.C. 102(b) as being anticipated by Pittenger (US 5,827,740) is maintained.

Applicant argues that Pittenger does not disclose an "effective amount" of a phosphodiesterase inhibitor sufficient to promote neurogenesis. Again, the term "effective amount", as outlined in MPEP 2173.05(c) III, is a very broad functional term, which in fact, is sometimes considered indefinite. Without more, the invention of

Pittenger is capable if performing the intended use. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 103 (Previous)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Graham (US 6,075,028) in view of Price (WO 200050568). This rejection is maintained and currently applies to claims 1-4 and 6-13.

Applicant argues that there is no reason why one skilled in the art would combine Graham and Price. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine is the treatment of the same disease taught in the references i.e. Alzheimer's disease. The rejection is maintained while a person having ordinary skill in the art would have been motivated to combine Graham and Price since they both teach

treating Alzheimer's disease and a patient with Alzheimer's qualifies as a patient in need of neurogenesis promotion. Again, a way of identifying increased numbers of new neurons would be to recognize improvement in the disease after administration. The limitation of "identifying increased numbers of new neurons" is met where there is a reasonable expectation of success in treating Alzheimer's patients with the combined sildenafil of Graham and the cellular therapy of Price.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WALTER E. WEBB whose telephone number is (571)270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Walter E Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612